Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 691076

TD Sample Number: **Import Sample Number**

This is an accurate reproduction of the original electronic record as of 01/22/2013

Sample Class: Normal Everyday Sample
Sample Origin: Domestic
Sample Basis: Other-Survl
Sample Flag:
Sample Type: Official
Collecting District: BLT-DO
Home District:
Orig C/R and Records To: NWE-DO
Collection PACs: 56R814

Product Name: Triamcinolone Acetonide (Glucocorticoid); Human - Rx/Single Ingredient; Sterile Liquid

Product Description: Preservative Free Triamcinolone Acetonide in sterile 1 mL glass vials with red over cap.

Collection Reason: Directed assignment from Office of Emergency Operations. Collected for sterility testing under CP 7356.R814. Product is compounded by New England Compounding Center (NECC). Reported under FACTS 1459760, OP ID 6417495.

Lab: SAN-LAB
Split Num: 0
Date Received: 10/17/2012
Date Out of Lab: 01/22/2013
District Conclusion:
District Conclusion Made By:
District
Disposition Reason:
Disposition Authorized By:
Disposition Authorized Date:

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SAN-MICRO	56R814		MIC		3 - Adverse Findings	Completed

Lab Conclusion

Bacillus lentus found in Sub 2.
Bacillus subtillus/amloliquefaciens/atrophate found in Sub 6.
Bacillus circulans and Bacillus firmus/Brevibacillus choshinensis foune in Sub 7.
No growth observed in Sub 1 and 10.
Suitability tests satisfactory.
Controls satisfactory.

Lab Conclusion Date
01/22/2013

Lab Conclusion Made By
Lau,Henry K

DKL
Acting LD
2/7/2013

FDA_E00482926

FLAG Original

ANALYST WORKSHEET	1. PRODUCT: Triamcinolone Acetonide, 40 mg / mL injectable	2. SAMPLE NUMBER: 691076

3. SEALS	4. DATE REC'D	5. RECEIVED FROM	6. DISTRICT OF LABORATORY
Intact	10/17/2012	James Gilchrist	SANLAB

7. DESCRIPTION OF SAMPLE

One plastic bag id'd as "691076 10/15/12 BRY", officially sealed and id'd as "691076 10/16/12 BRIAN R. YAUN, INVESTIGATOR" and containing a total of 10 subs, subnumbered 1-10, each sub id'd as "691076 10/15/12 BRY". The sample was received intact and at room temperature.

8. NET CONTENTS

☐ NOT APPLICABLE — DECLARE/UNIT: 1 ML

☒ NOT DETERMINED — AMOUNT FOUND:

____ UNITS EXAMINED — % OF DECLARED:

9. LABELING

ORIGINAL(S) SUBMITTED: 3

COPIES SUBMITTED

LABELING NONE FOUND ☐ CODES NONE FOUND ☐

10. SUMMARY OF ANALYSIS

Container: Clear colourless glass vial, approximately 3.5 cm tall and 1.5 cm in diameter at base, capped with a foil-lined septum, and a red plastic lid.

Labeling: A white paper sticker, printed in black ink, includes in parts: product description, amount, preparation instructions, lot number, and expiration date.

Product: A suspension of white paste in a clear fluid. When shaken, the product is a milky white.

Method and Analysis: See Methods Page 3.

Results

All controls satisfactory.
Bacillus *lentus* isolated from sub 2.
Bacillus *subtilus/amloliquefaciens/atrophate* isolated from sub 6.
Bacillus *circulans* and Bacillus *firmus*/Brevibacillus *choshinensis* isolated from sub 7.
No growth detected from subs 1 and 10.
For system suitability, see data from sample 691077 (attachment A).

11. RESERVE SAMPLE

Investigator's seal identified as broken by "JY 10/17/12". Remainder of subs 1, 2, 6, 7, and 10 and subs 3, 4, 5, 8, 9 intact were identified as "691076 10/18/12 APL", placed in original packaging identified as "691076 10/18/12 APL" sealed as "691076 10/22/12 Jonathon A. Yenovkian", and returned to Jim Gilchrist, Sample custodian on 10/23/12. Samples were stored locked in room 165.

12. ANALYST SIGNATURE

Analyst(s)	Broke Seal	Lead	Responsibilities	Signature(s)
Jon Yenovkian	☒	☒	Sample analysis	
Andrew Lin	☐	☐	Sample analysis	
Teresa Lee	☐	☐	Vitek identification	
Jenny Yee	☐	☐	Vitek identification	
Eileen Liu	☐	☐	Growth carrythough	
Elaine Yeh	☐	☐	Growth carrythough	
HENRY LAU			received and return sample	

13. WORKSHEET CHECK

a. BY: b. DATE: 1/22/13

14. DATE REPORTED

1/22/13

Page 1 of 9 Pages

e431 Attachments A-L

CODES	1. PRODUCT	2. SAMPLE NUMBER
	Triamcinolone Acetonide, 40 mg / mL injectable	691076

Printed in black ink in on the white sticker affixed to each sub, 1-10, on the center far left:
"Lot # 06062012// Discard after 12/3/2012"

Analyst(s)

FDA_E00482928

GENERAL CONTINUATION SHEET	PRODUCT Triamcinolone Acetonide 40 mg/mL	SAMPLE NO. 691076

Please continue your entry below

Methods:

USP35-NF30 online, Chapter <71> Sterility Tests, test by direct inoculation
Subs 1, 2, 6, 7, and 10 analyzed individually

Procedure:

Product was tested by direct inoculation. Product testing performed in a horizontal laminar flow hood certified in compliance with Class 100 conditions, located in a controlled environment clean room as described in Federal Standard No. 209E.

Product of subs 1, 2, 6, 7, and 10 were analyzed via direct inoculation as follows:

The septum covered top of each tested sub was decontaminated by dipping it into a 10% bleach solution, allowing it air dry, and wiped down with a sterilized paper towel soaked with sterile isopropanol. Before product was analyzed, each vial was shaken to resuspend a precipitate. A sterile needle with syringe was used to puncture the septum cap and withdraw the entire contents of the vial, approximately 1 mL, and half of the fluid (approximately 0.5 mL) was inoculated into a 100 mL bottle of both Soybean Casein Digest (SCD) and the other half was inoculated into a bottle Fluid Thioglycollate Medium (FT).

of JY 2/7/13

For all subs, FT was incubated at 33± 2°C, SCD at 23±2°C, for 14 days, or until growth was observed.

Media, environmental, system, and equipment controls run in parallel with sterility test:

Two unopened vessels of each medium incubated in parallel with product test media, used as negative media control.

Two opened vessels of each medium, two opened SCD agar plates, and two opened Potato Dextrose Agar plates were placed in working areas of the hood and a second of the described open media controls were placed on the bench-top during analysis. RODAC plates were used to test hood surface, bench surface, and floor of the clean-room, as well as the analysts' gloves and gowns, and two STA air sampling plates of the hood environment during testing, all incubated in parallel as environmental controls.

Two syringes with needles from the same sterilization lot used during analysis were used to withdraw SCD and FT, which were then incubated in parallel as negative equipment controls.

JY 1/16/13

ANALYST(S)	ANALYST NO.	PAGE 3 OF 4 PAGES

FORM FDA 431a (5/84)

PRODUCT: Triamcinolone AC 40 mg/mL injectable

SAMPLE NO. 691076

Primary Media: Fluid Thio/SCD

Sterility Daily Observation Record

Date Started: 10/18/12

ANALYST(S): Ada Y. Y. Jamil Hyder

Sub No.	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Final Results
1	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	See pg 5 for details
2	- -	- -	- -	- -	- -	- +	- +	- +	- +	- +	- +	- +	- +	- +	See pgs 5 & 6 for details
6	- -	- -	- -	- -	- -	- +	- +	- +	- +	- +	- +	- +	- +	- +	↓
7	- -	- -	- -	- -	- -	- +	- +	- +	- +	- +	- +	- +	- +	- +	
10	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	See pg 5 for details
Date	10/19	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	
Analyst	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	

"+" = growth
"-" = no growth
"T" = sample-induced turbidity
"NC" = not checked

Fluid Thio incubated in Incubator # 1471 @ 33°± 2°C.
SCD incubated in Incubator # 142 @ 23°± 2°C.

H = Holiday, W= Weekend, L=Leave

Remarks:

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MICRO STERILITY1, V1.0 (Effective Date 3/14/2005)

FDA_E00482930

MICRO STERILITY1, V1.0 (Effective Date 3/14/2005)

ANALYST(S) Qais Ugla Eng

PAGE 5 OF 9 PAGES

Primary Media: Fluid Thio/SCD

Sterility Daily Observation Record

Date Started: 11/1/12

PRODUCT Triamcinolone AC 40 mg/ml

SAMPLE NO. 691076

Sub No.	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Final Results
1	- -	- -	- -	- -	- -	- -	- -								No growth detected
2	-	-	-	-	-	-	-								See pg 6 for details
6	-	-	-	-	-	-	-								↓
7	-	+													
10	- -	- -	- -	- -	- -	- -	- -								No growth detected
Date	11/2/12	11/3/12	11/4/12	11/5/12	11/6/12	11/7/12	11/8/12								
Analyst	Eg	Eg	Eg	Eg	Eg	Eg	Eg								

"+" = growth
"-" = no growth
"T" = sample-induced turbidity
"NC" = not checked

Fluid Thio incubated in Incubator # 1471 @ 33°± 2°C.
SCD incubated in Incubator # 142 @ 23°± 2°C.

H = Holiday, W= Weekend, L=Leave

Remarks: Sub passage due to product induced turbidity.

FDA_E00482931

ANALYST(S) Lauren Jennings-Hyde

PRODUCT Triamcinolone AC 40 mg/mL

SAMPLE NO. 691076

PAGE 6 OF 9 PAGES

Isolate VITEK Record

Date Tested: Nov 2, 2012 + 11/7/12 + 10/28/12 + 11/9/12

Isolate ID	Gram Stain[1]	VITEK Purity Check Saline[2]	VITEK Purity Check Organism[3]	VITEK / API 20E Results	VITEK Attachment(s)	Summary
691076 TSB2 (day 1	R+	[redacted]	P	Bacillus lentus	B	organism identified
B. subtilis	R+	[redacted]	P	Bacillus subtilis	C+D	control acceptable
691076 TSB 6	R+	[redacted]	P	Bacillus subtilis/ amyloliquefaciens & atrophaeus	E+F	organism identified
B. subtilis control	R+	[redacted]	P	Bacillus subtilis	G+H	control acceptable
691076-TSB7	R+	[redacted]	P	Bacillus circulans	I	organism identified
B. subtilis	R+	[redacted]	P	Bacillus subtilis	J+K	control acceptable
691076 Thio TBC	R+	[redacted]	P	Bacillus firmus/ * Brevibacillus choshinensis	L	organism identified
		[redacted]				
		[redacted]				
		[redacted]				
		[redacted]				
		[redacted]				
Saline	[redacted]	NG	[redacted]	[redacted]	[redacted]	control acceptable

1 "+"=Gram Positive, "-" Gram Negative, "R"=Rods, "C"=Cocci
2 G = Growth, NG = No Growth
3 P = pure culture, M = mix culture, NG = No Growth

* low discrimination organism

MICRO WS 4.17, V1.0 (Effective Date 12/7/12)

FDA_E00482932

Sterility Fluid Thio/SCD Control Daily Observation Record

Date Started: 10/18/12

PRODUCT: Triamcinolone AC 40mg/ml

SAMPLE NO.: 691676

Control	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Final Results
Unopened media 1	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	Controls Acceptable
2 each 2	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	
Exposed media R	- -	- -	- -	- -	- -	- -	- +	- +	- +	- +	- +	- +	- +	- +	Right Bench scp turbid Unable to identify.
laminar hood, 2 each L	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	
Exposed media,	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	Controls acceptable
bench top, 2 each	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	
Scissors Dip, 2 each															
Forceps Dip, 2 each															
Syringe Dip 1	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	Controls Acceptable
2	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	
Date	10/19	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	
Analyst	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	JY	

"+" = growth
"-" = no growth
"T" = sample-induced turbidity
"NC" = not checked

Fluid Thio incubated in Incubator # 1471 @ 33°± 2°C.
SCD incubated in Incubator # 142 @ 23°± 2°C.

H = Holiday, W= Weekend, L=Leave

Remarks: Reviewed by David Jones, Supv Micro

ANALYST(S): Chu Y. L. Jones

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MICRO STERILITY2, V1.0 (Effective Date 3/14/2005)

FDA_E00482933

Sterility Agar Plate Control Daily Obeservation Record

Analyst(s) [illegible]

Incubator @ 33±2° C: 1471
Incubator @ 23±2° C: 142
Date started: 10/18/12

= # of distinct colonies
"-" = No Growth
"T" = sample induced turbidity
"NC" = not checked

SCD agar incubated @23±2° C on days 1-3 and 33±2° C on days 4 and 5.
PDA plates incubated @23±2° C for days 1-5
RODAC plates incubated @33±2° C for days 1 and 2.

PRODUCT: Triamcinolone AC 40 mg/mL Injectable

SAMPLE NO.: 691096

Negative Control		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Exposed SCD plates, hood	L	-	-	-	-	-	
	R	-	-	-	-	-	
Exposed SCD plates, benchtop	L	-	-	-	-	-	
	R	-	-	-	-	-	
Air sampler (SCD agar)	1	1	1	1	1	1	1
	2	1	1	1	1	1	1
Exposed PDA plates, hood	L	-	-	-	-	-	
	R	-	-	-	-	-	
Exposed PDA plates, benchtop	L	-	-	-	-	-	
	R	-	-	-	-	-	
RODAC plates, hood	L	-	-	-	-		
	R	-	-	-	-		
RODAC plates, floor	L	-	-	-	-		
	R	-	-	-	-		
	C	-	-	-	-		
RODAC plates, wall	L	-	-	-	-		
	R	-	-	-	-		
RODAC plates, benchtop	L	-	-	-	-		
	R	1	1	1	1		
Analyst APL gloves	L	-	-	-	-		
	R	-	-	-	-		
Analyst APL arms and torso	A	-	-	-	-		
	T	-	-	-	-		
Analyst APL head and thigh	H	1	1	1	1		
	T	-	-	-	-		
Analyst JY gloves	L	-	-	-	-		
	R	-	-	-	-		
Analyst JY arms and torso	A	-	-	-	-		
	T	-	-	-	-		
Analyst JY head and thigh	H	-	-	-	-		
	T	-	-	-	-		
Positive controls							
PDA inoculated w/ *C. albicans*		+					
SCD inoculated w/ P.aeruginosa		+					
RODAC inoculated w/ P.aeruginosa		+					
Checking Date		10/19	10/20	10/21	10/22	10/23	10/24
Analyst Initials		JY	JY	JY	JY	JY	JY

Final results: Bioburden below alert limits. Controls Acceptable

Positive controls acceptable

Remarks

FDA_E00482934

PRODUCT	SAMPLE NO.
Triamcinolone AC 40 mg/mL injectable	691076

Sterility QA Record

Media	Vol/ Unit	Autoclave No. or Lot No.	Reagent	Autoclave No. or Lot No.
Fluid Thioglycollate	100 mL	5112	Vitek GNI Cards	
Soybean Casein Digest	100 mL	5101, 12243 (Hardy)	VitekS GP cards	98169512
Diluting Fluid A	100 mL		VitekS GN cards	98163559
Diluting Fluid D	100 mL		VitekS BCL cards	98181866
Rodac Plates	12 mL	5096	Saline for VitekS	98136269
SCD Plates	20 mL	5096, 5144	Blood Agar	98184337, 98187823
SCD Slants	5 mL		Blood Agar	98187821, 98187822
PDA w/40 ppm chlortet	20 mL	5098	Blood Agar	98187816
MacConkey Plates	20 mL	5140	Gram stain kit	98163425
Air sampler plate	80 mL	5096	0.85% Saline	4485
Malt Extract Agar		5108, 12277 (Hardy)		

Equipment	Autoclave No. or Lot No.
6-Place Manifold with 0.45 µm filter and 0.22 µm bleed filter	
3-Place Manifold with 0.45 µm filter and 0.22 µm bleed filter	
13 mm Swinney Unit with 0.22 µm filter and 20 Gauge needle	
3 cc syringes	4823
Air Sampler Probe	5117
Carboy	
Forceps	
Gown Sets	5117
Mop head	5118
Paper towels	
Scissors	
ATCC 6633 B. subtilis	043889
ATCC 16404 A. brasiliensis	160336
Microscope	1562

Analyst(s) Elaine Yan, Jenny T. Yee

FDA_E00482935

691076
12/14/12
JY

Attachment A

GENERAL CONTINUATION SHEET | PRODUCT: Triamcinolone Acetonide 40 mg/mL | SAMPLE NO. 691077

BACTERIOSTASIS AND FUNGISTASIS

Date Started : 11/11/12

1. Procedure: less than 100 cells/spores each of test organisms 1, 2, 3, 5, & 6 were added to bottles containing 100 mL of Fluid Thioglycollate medium and 10 (mL)/gm product sample; less than 100 cells/spores each of test organisms 1, 2, 3, 4, & 5 were added to bottles containing 100 mL of Soybean Casein Digest medium and 10 (mL)/gm product sample. Both sets of media product were then incubated as in product sterility analysis. Similar sets of media without product were also inoculated as above and incubated with test bottles.

2. Modification:
Performed post-analysis
P. aeruginosa, S aureus, C. albicans, and C. sporogenes not tested for suitability
Approved
Supv Micro 11/11/12

3. Results:
Product is bacteriostatic for Aspergillus niger. All other controls satisfactory.

Test Organisms	Media With Product		Media Without Product	
	Thio. 33°C	SCD 23°C	Thio. 33°C	SCD 23°C
1. *Pseudomonas aeruginosa* ATCC#	Not tested 11/30/12 JY			
2. *Bacillus subtilis* ATCC# 6633 Lot# 043689	+	+	+	+
3. *Staphylococcus aureus* ATCC#	Not tested 11/30/12 JY			
4. *Aspergillus niger* ATCC# 16404 Lot#160336		−		+
5. *Candida albicans* ~~ATCC#~~	Not tested 11/30/12 JY			
6. *Clostridium sporogenes* ATCC#	Not tested 11/30/12 JY			

ANALYST(S): Jonathan Yen

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FORM FDA 431a (SAN-DO MICRO STERILITY4, V1.0) Effective Date 3/1/2005

FDA_E00482936

691076
11/1/12
TL

Attachment B
U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 05:37 PDT
Autoprint

Isolate Group: 691076 TSB2 1L-1 691076 TSB 2, colony ①

Bionumber: 1253101014110220
Selected Organism: Bacillus lentus

Comments:	

Identification Information	Card:	BCL	Lot Number:	239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed:	Nov 1, 2012 06:03 PDT	Status:	Final	Analysis Time: 14.25 hours
Selected Organism	90% Probability		Bacillus lentus		
	Bionumber:	1253101014110220			Confidence: Good identification
SRF Organism					
Analysis Organisms and Tests to Separate:					
Analysis Messages:					
Contraindicating Typical Biopattern(s)					
Bacillus lentus	AMAN(80),LeuA(71),APPA(3),AlaA(15),NaCl 6.5%(12),				

Biochemical Details

1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	-	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	(-)
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	+	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

FDA_E00482937

691076
11/1/12
TL

Attachment C

U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 10:54 PDT
Printed by: LabTech

Isolate Group: B. subtilis-1 B. subtilis

Bionumber: 1372065605453261
Selected Organism: Bacillus subtilis

Comments:	

Identification Information	Card:	BCL	Lot Number:	239266620	Expires:	Apr 2, 2014 13:00 PDT
	Completed:	Nov 1, 2012 06:53 PDT	Status:	Final	Analysis Time:	14.25 hours
Selected Organism	95% Probability		Bacillus subtilis			
	Bionumber:	1372065605453261			Confidence:	Very good identification

SRF Organism

Analysis Organisms and Tests to Separate:

Bacillus subtilis/amyloliquefaciens/atrophaeus
Bacillus amyloliquefaciens
Bacillus atrophaeus
Bacillus subtilis

Analysis Messages:

See product information for additional information.

Contraindicating Typical Biopattern(s)

Bacillus subtilis/amyloliquefaciens/atrophaeus	dMNE(88),GLYG(69),BGAL(25),INU(25),

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

691076
11/1/12
TL

Attachment D

U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 10:54 PDT
Printed by: LabTech

Isolate Group: B. subtilis-1 B. subtilis

Bionumber: 1372065605453261
Selected Organism: Bacillus subtilis

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	+	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	(-)	13	TyrA	+	14	BNAG	-
15	APPA	(-)	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	+	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	(+)	29	MTE	-	30	GlyA	(+)	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	+	46	AGLU	+	47	dTAG	-	48	dTRE	+
50	INU	+	53	dGLU	+	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment E

U.S. FDA - San Fransisco District

691076
1/8/13
JKJ

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:07 PST
Printed by: Labtech

Isolate Group: 691076 TSB 6-1

Bionumber: 1267150715452220
Selected Organism: Bacillus subtilis/amyloliquefaciens/atrophaeus

Comments:	

Identification Information					
	Card: BCL	**Lot Number:** 239266620	**Expires:** Apr 2, 2014 13:00 PDT
	Completed: Nov 9, 2012 07:07 PST	**Status:** Final	**Analysis Time:** 14.25 hours
Selected Organism	94% Probability	**Bacillus subtilis/amyloliquefaciens/atrophaeus**	
	Bionumber: 1267150715452220	**Confidence:**	Very good identification

SRF Organism

Analysis Organisms and Tests to Separate:

Bacillus subtilis/amyloliquefaciens/atrophaeus
Bacillus amyloliquefaciens
Bacillus atrophaeus
Bacillus subtilis

Analysis Messages:

See product information for additional information.

Contraindicating Typical Biopattern(s)

Bacillus subtilis/amyloliquefaciens/atrophaeus	BNAG(19),LeuA(88),APPA(17),

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment F

U.S. FDA - San Fransisco District

691076
1/8/13
JKy

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:07 PST
Printed by: Labtech

Isolate Group: 691076 TSB 6-1

Bionumber: 1267150715452220
Selected Organism: Bacillus subtilis/amyloliquefaciens/atrophaeus

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	-	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	+
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	+	22	INO	-	24	MdG	+
25	ELLM	-	26	MdX	-	27	AMAN	-	29	MTE	+	30	GlyA	+	31	dMAN	+
32	dMNE	+	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	+	46	AGLU	+	47	dTAG	-	48	dTRE	+
50	INU	-	53	dGLU	+	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment G

U.S. FDA - San Fransisco District

691076
1/8/13
JKy

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:08 PST
Printed by: Labtech

Isolate Group: B subtilis control-1

Bionumber: 3377161405556261
Selected Organism: Bacillus subtilis

Comments:	

Identification Information					
	Card:	BCL	**Lot Number:** 239266620	**Expires:**	Apr 2, 2014 13:00 PDT
	Completed:	Nov 9, 2012 07:07 PST	**Status:** Final	**Analysis Time:**	14.25 hours
Selected Organism	93% Probability	**Bacillus subtilis**			
	Bionumber: 3377161405556261			**Confidence:**	Very good identification

SRF Organism

Analysis Organisms and Tests to Separate:

Bacillus subtilis/amyloliquefaciens/atrophaeus
Bacillus amyloliquefaciens
Bacillus atrophaeus
Bacillus subtilis

Analysis Messages:

See product information for additional information.

Contraindicating Typical Biopattern(s)

Bacillus subtilis/amyloliquefaciens/atrophaeus	BNAG(19),dMNE(88),APPA(17),GLYG(69),BGAL(25),

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

FDA_E00482942

Attachment H

U.S. FDA - San Fransisco District

691076
1/8/13
JKy

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:08 PST
Printed by: Labtech

Isolate Group: B subtilis control-1

Bionumber: 3377161405556261
Selected Organism: Bacillus subtilis

Biochemical Details																	
1	BXYL	+	3	LysA	(+)	4	AspA	-	5	LeuA	(+)	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	+
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	(+)	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	(-)	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	+	46	AGLU	+	47	dTAG	-	48	dTRE	+
50	INU	-	53	dGLU	+	54	dRIB	+	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment I

U.S. FDA - San Fransisco District

691076
1/8/13
JKy

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:11 PST
Printed by: Labtech

Isolate Group: 691076 TSB7-1

Bionumber: 5652540135112220
Selected Organism: Bacillus circulans

Comments:	

Identification Information					
	Card:	BCL	Lot Number: 239242810	Expires:	Aug 7, 2013 13:00 PDT
	Completed:	Oct 29, 2012 01:59 PDT	Status: Final	Analysis Time:	14.25 hours
Selected Organism	88% Probability		Bacillus circulans		
	Bionumber:	5652540135112220		Confidence:	Acceptable identification

SRF Organism	
Analysis Organisms and Tests to Separate:	
Analysis Messages:	
Contraindicating Typical Biopattern(s)	
Bacillus circulans	AMAN(93),NAG(92),ELLM(85),TTZ(88),INU(81),CDEX(77),dTRE(89),

Biochemical Details

1	BXYL	+	3	LysA	-	4	AspA	+	5	LeuA	(-)	7	PheA	+	8	ProA	+
9	BGAL	+	10	PyrA	-	11	AGAL	+	12	AlaA	-	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	+	21	GLYG	(-)	22	INO	-	24	MdG	+
25	ELLM	-	26	MdX	-	27	AMAN	-	29	MTE	+	30	GlyA	-	31	dMAN	-
32	dMNE	+	34	dMLZ	+	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	+	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

FDA_E00482944

Attachment J

U.S. FDA - San Fransisco District

691076
1/8/13
JKY

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:12 PST
Printed by: Labtech

Isolate Group: B. subtilis-1

Bionumber: 7373151605442261
Selected Organism: Bacillus subtilis

Comments:	

Identification Information					
	Card: BCL	**Lot Number:** 239242810	**Expires:**	Aug 7, 2013 13:00 PDT
	Completed: Oct 28, 2012 08:02 PDT	**Status:** Final	**Analysis Time:**	14.25 hours
Selected Organism	87% Probability **Bacillus subtilis**			
	Bionumber: 7373151605442261		**Confidence:**	Acceptable identification
SRF Organism				

Analysis Organisms and Tests to Separate:

Bacillus subtilis/amyloliquefaciens/atrophaeus
Bacillus amyloliquefaciens
Bacillus atrophaeus
Bacillus subtilis

Analysis Messages:

See product information for additional information.

Contraindicating Typical Biopattern(s)

Bacillus subtilis/amyloliquefaciens/atrophaeus	dMNE(88),APPA(17),AspA(3),LysA(3),BGAL(25),AGLU(94),

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment K

U.S. FDA - San Fransisco District

K911076
1/8/13
JKY

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:12 PST
Printed by: Labtech

Isolate Group: B. subtilis-1

Bionumber: 7373151605442261
Selected Organism: Bacillus subtilis

Biochemical Details

1	BXYL	+	3	LysA	+	4	AspA	+	5	LeuA	+	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	(-)	19	dGAL	-	21	GLYG	+	22	INO	(-)	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	+	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	(-)	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	+	46	AGLU	-	47	dTAG	-	48	dTRE	+
50	INU	-	53	dGLU	+	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

FDA_E00482946

Attachment L

691076
1/8/13
JKy

U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Jan 8, 2013 17:14 PST
Printed by: Labtech

Isolate Group: 691076 Thio7 BCL-1

Bionumber: 5323101104110020
Selected Organism: Low Discrimination Organism

Comments:	

Identification Information	Card:	BCL	Lot Number:	239266620	Expires:	Apr 2, 2014 13:00 PDT
	Completed:	Nov 7, 2012 07:05 PST	Status:	Final	Analysis Time:	14.00 hours

Selected Organism	Low Discrimination Organism		
	Bionumber: 5323101104110020	Confidence:	Low discrimination

SRF Organism	

Analysis Organisms and Tests to Separate:

Low Discrimination Organism	
Bacillus firmus	OX(0),
Brevibacillus choshinensis	OX(100),

Analysis Messages:

Contraindicating Typical Biopattern(s)

Bacillus firmus	APPA(6),BGLU(19),BXYL(16),ESC(21),MTE(8),dGLU(75),BMAN(1),
Brevibacillus choshinensis	BGLU(24),BXYL(12),GlyA(76),AGLU(12),MTE(1),BMAN(12),

Biochemical Details

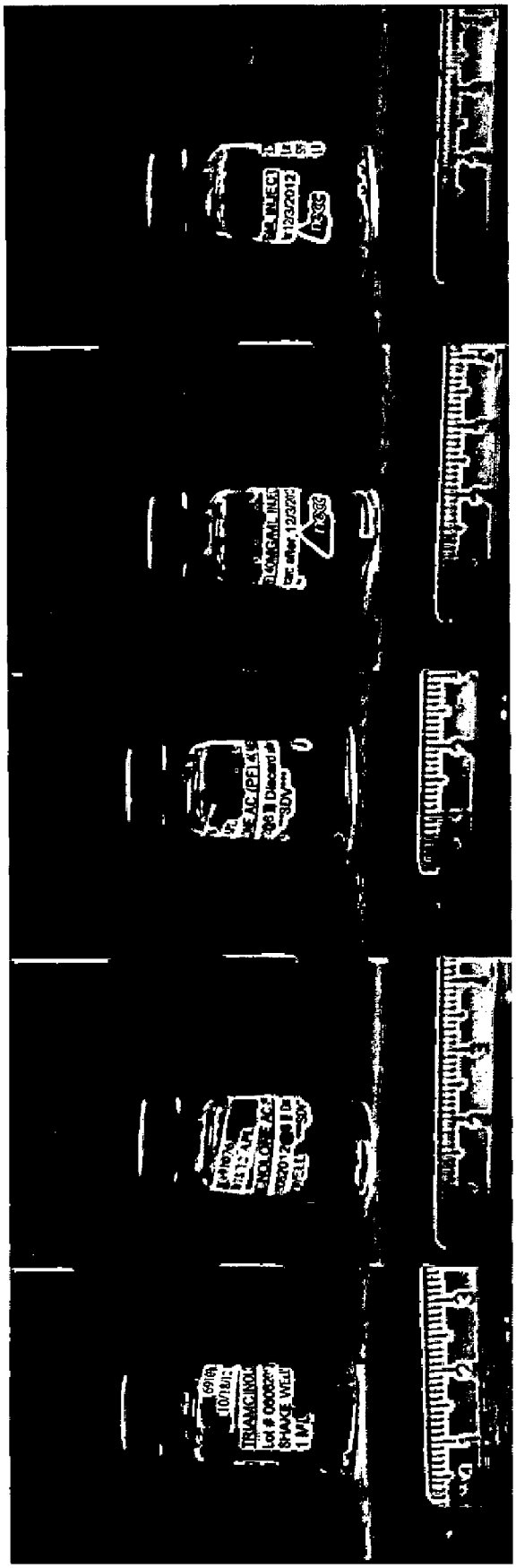
1	BXYL	+	3	LysA	-	4	AspA	+	5	LeuA	(+)	7	PheA	+	8	ProA	-
9	BGAL	-	10	PyrA	(+)	11	AGAL	-	12	AlaA	+	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	+	30	GlyA	-	31	dMAN	-
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Labeling

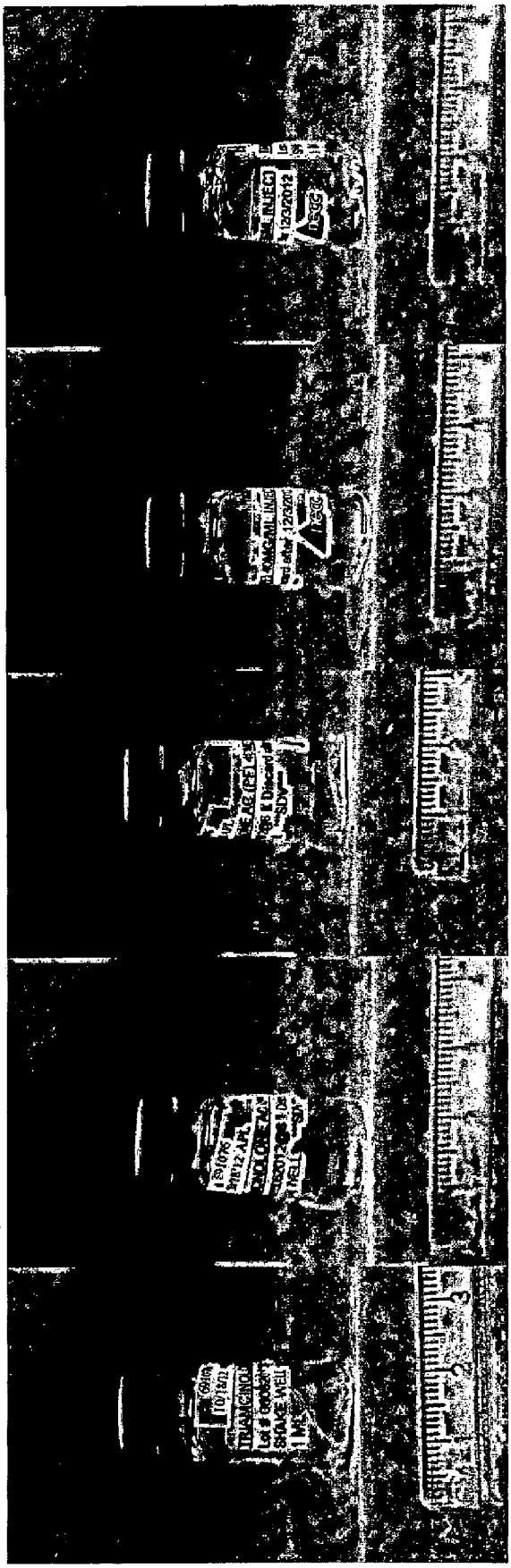
691076
10/18/12
apc



Pictures verified by
[signature] 10/22/12

Labeling

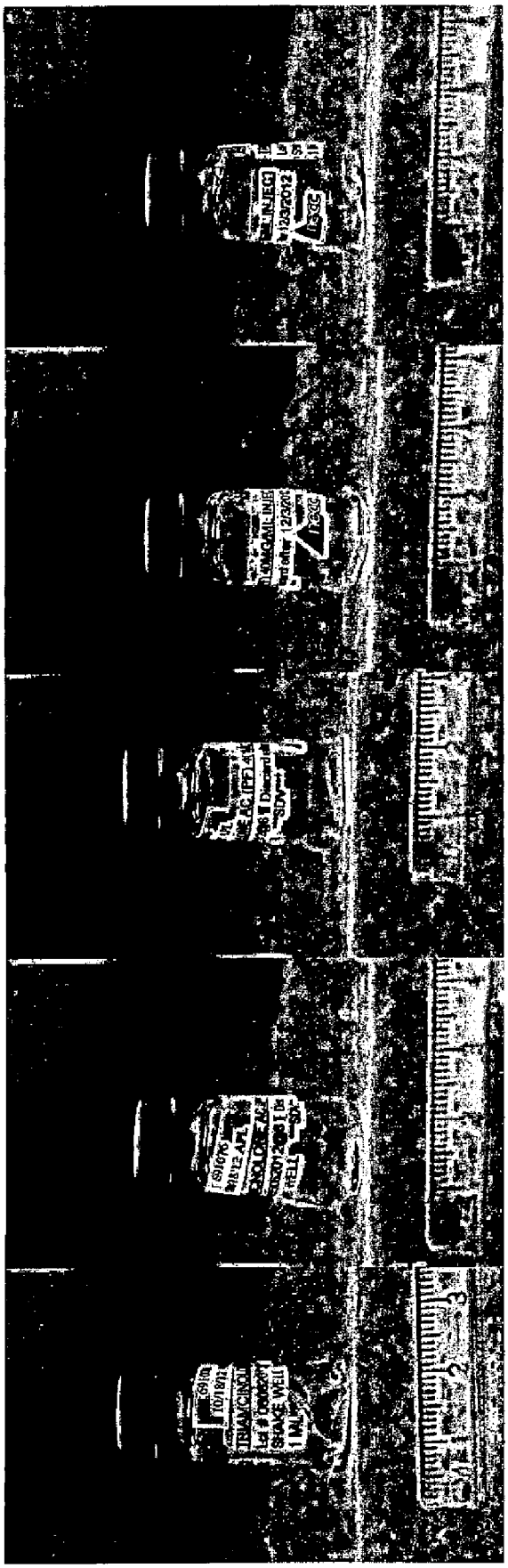
691076
10/15/12
apc



Picture verified by
10/22/12

Labeling

691076
10/13/12
apc



Picture verified by
[signature] 10/22/12

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 691076

This is an accurate reproduction of the original electronic record as of 10/17/2012

Micro
MIC
691076 56R814

Flag | **Flag Remarks**

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Other-Survln	Official	13206564	In Progress

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3003623877	10/16/2012	64LCK6!	Manufacturer	56R814	

Compliance Num	Country of Origin
	United States

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	BLT-DO			Ambient

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
No				NECC

Date 10/17/12
No. of Pkg. 1
Pkg. Type BAG
Location 145-498
Initials
☐ Repacked by Sample Custodian

Product Description
Preservative Free Triamcinolone Acetonide in sterile 1 mL glass vials with red over cap.

Product Label
See continuation.

Reason for Collection
Directed assignment from Office of Emergency Operations. Collected for sterility testing under CP 7356.R14. Product is compounded by New England Compounding Center (NECC). Reported under FACTS 1459760, OP ID 6417495.

MFG Codes
06062012@6

Expiration Date
12/3/2012

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Manufacturer	3003623877	
Carilion Surgery Center NRV, LLC	2901 Lamb Circle Christiansburg, VA 24073 US	Dealer	3009805154	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
10 vials	$ 80.00	FDA484		

Description of Sample
Sample consists of 10 - 1 mL vials of Triamcinolone Acetonide, 40 mg / mL.

Method of Collection
Sample collected from dealer firm's quarantine area. This product was under recall by the manufacturing firm.

How Prepared
See continuation.

Collector's Identification on Package and/or Label
"691076 10/15/12 BRY" + Sub Number (1 - 10)

Collector's Identification on Seal
"691076 10/16/12 Brian R. Yaun"

Sample Delivered To
UPS Tracking Number 1ZA4799R0192240343

Date Delivered	Orig C/R & Records To
10/16/2012	NWE-DO
Lab w/Split Sample	**Lab**
0	SAN-LAB

Document Number	Document Date	Document Type	Document Remarks
1	10/15/2012	Affidavit	Signed affidavit from Ms. Shawna L. Hall, Adminstative Director at dealer firm for sample collected and records provided. (2 pages)

ANALYSES

- ✓ Microbiology
- ___ Decomposition
- ___ Chemistry
- ___ Seafood Fl
- ___ Metals
- ___ Other ___

FDA_E00482951

2	08/24/2012	Invoice	NECC Invoice 226956 dated 8/24/12 showing the shipment of 30 units of TRIAM AC/40/1 PF TRIAMCINOLONE ACETONIDE, 40 MG/ML from New England Compounding Center, Woburn, MA to New River Valley Surgery Center, Christinasburg, VA. (1 page)
3	08/24/2012	Other	Packing Slip for Invoice #226956 dated 8/24/12 showing inclusion of 30 vials of TRIAMCINOLONE ACETONIDE 40 MG/ML, PRESERVATIVE FREE, 1ML from New England Compounding Center, Woburn, MA to New River Valley Surgery Center, Christiansburg, VA. (1 page)
4	08/22/2012	Other	Dealer firm purchase order 991507 dated 8/22/12 to NECC for 30 vials of Triamcinolone 40 mg/ml p/f. (1 page)
5		Other	Digital photos of labeling taken during sample collection. (4 pages)
6		Other	Digital cd containing photos taken during sample collection. (1 page)

Remarks
See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
$0.00	No Charge	No	No	Brian R Yaun

Name of Signer	Date & Time of Signature	Meaning
	ET	

FDA_E00482952

Continuation:

Product Label
This product is packed in 1 mL glass vials with a red over cap and labeled in part. "***TRIAMCINOLONE AC (PF) 40MG/ML***LOT # 06062012@6***SDV***necc*** 1mL***

How Prepared
Each sub identified on bottom of glass vial with yellow sticker containing sample number, date of collection, collectors ID and sub number. Subs placed into individual whilpack bags and closed. Each whirlpack bag placed into a single whirlpack bag and officially sealed in presence of dealer firm. See remarks.

Remarks
On 10/16/12, I broke the official seal to prepare the sample for shipment to the lab. Each identifying sticker was taped to the vial. Each vial wrapped in bubble wrap and taped shut before being placed into an individual whirlpack bag. Each bag rubber banded shut and placed into one large Whirlpack bag. Large whirlpack bag officially sealed and identified with black sharpie marker on exterior of bag with sample number, date of collection and collectors ID.

Sample placed into carton along with sample 691077 and additional bubble wrap to protect during transit. Photocopy of broken seal included in FDA 525 along with CR for lab.

Manufacturing firm documents do not identify the lot number that was actually shipped to dealer firm. This is the only shipment of this product received by the dealer firm.

FDA_E00482953